



Internal Medicine

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Diplomate American
Board of Internal Medicine
Debra K. Hinkle, RN, MS, ANP

8/21/00 NOV 13 P5:28

FAX COVER

Date: November 13th 2000

To: Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn drive
Rockville, MD 20857

Regarding docket number 00P-1499/CP1

Fax number: 301-827-6870

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To whom it may concern:

I am an internist with a long standing interest in the treatment of irritable bowel syndrome. I have published three books on this topic for IBS sufferers. I am writing at this time to express my concerns regarding the adverse publicity surrounding Lotronex. In my experience Lotronex is a very safe and effective medication for treatment in appropriate patients who suffer and endure symptoms of IBS. I have had a chance to review the literature on Lotronex in-depth. I do not feel the patient deaths attributed to Lotronex were related to the use of this medication. Additionally, I doubt that the patients were appropriately selected for the use of Lotronex.

I feel that the FDA would be doing a great disservice to IBS sufferers by withdrawing Lotronex before a more thorough investigation. I feel confident that the FDA will consider all points of view regarding this matter, not just sensationalized, misrepresentation of the facts.

Sincerely,

Gerard L. Guillory MD

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